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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Continuation of 3. NOTE:

The proposed amendment introduces the new limitation "suppressing the production or activity of the growth-promoting gene, thereby inducing the CNS progenitor cells to differentiate into neurons and/or astrocytes." Accordingly, the proposed amendment, if entered, would require new search and consideration, in view of the new limitation. The claims encompass administering the conditionally-immortalized human CNS progenitor cells to the brain and therefore new consideration is required with regard to techniques that regulate *in vivo* gene expression in the brain. The instant application claims priority to September 1996.

Continuation of 11. The request for reconsideration has been considered but does NOT place the application in condition for allowance because:

Applicants arguments are moot because they rely on the proposed amendment which has not been entered.

With regard to the rejection of Claims 12-17 and 33 under 35 U.S.C. 112, first paragraph, Applicants note, at page 4 of the response, that the Office Action alleges that the specification is not enabling because, at the time of the invention, successful implementation of cell therapy protocols and *ex vivo* gene therapy protocols were not routinely achievable by those skilled in the art. Applicants further note that, in order to reduce the issues and expedite prosecution, Claim 14, directed to a method of treating a subject has been cancelled. Applicants conclude that the Examiner's concerns with regard to the unpredictability of achieving a therapeutic effect by administration of the disclosed conditionally-immortalized CNS progenitor cells has been rendered moot. On the contrary, Claims 12, 16, 17, and 33 also encompass therapy, and in particular, therapy of humans having the particular pathological

conditions recited in Claim 17. There is no other disclosed utility for administering CNS progenitor cells to a human and therefore the specification must enable this aspect of the claimed invention.

At page 5 of the response, Applicants assert that the specification enables the claimed invention by providing detailed examples demonstrating the preparation and characterization of conditionally-immortalized CNS progenitor cells, as well as specific examples for the production of differentiated cells. Applicants further assert that the specification provides, at page 20, guidance regarding compositions of such progenitor cells and routes of administration for *in vivo* delivery. However, the claims encompass therapy and the specification fails to enable the production of a therapeutic effect, for reasons of record. The specification discloses that the claimed method includes delivering conditionally-immortalized CNS progenitor cells to humans for treatment of various pathological conditions, and therefore the specification must adequately enable production of a therapeutic effect upon administration of the cells to a human patient.

Accordingly, the rejection of Claims 12-17 and 33 under 35 U.S.C. 112, first paragraph, is maintained for reasons of record.